REMARKS

In the Final Office Action mailed October 10, 2002, claims 1 and 14 were rejected on new grounds. Claims 1-9, 12, 14 and 15 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,083,248 to Thompson et al. (Thompson). Thompson is characterized as acquiring data from two or more implantable medical devices for transmission to a centralized computing resource. Further, Thompson is deemed to inherently compare acquired data to a model. Alternatively, Thompson is characterized as disclosing the claimed invention except for analyzing data according to a physiological model. The Office Action relies upon Scarantino (U.S. Patent No. 6,402,689) as disclosing the analysis of physiological data according to a physiological model.

Claims 1-9 and 12 were also rejected as obvious under 35 U.S.C. §103(a) over U.S. Patent No. 5,720,770 to Nappholz et al. (Nappholz) in view of Thompson. Nappholz was considered to inherently disclose analyzing physiological data according to a suitable model.

Claims 10 and 19 were rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,186,170 to Varrichio et al. (Varrichio). Claims 11 was rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,899,931 to Deschamp et al. (Deschamp). Claims 16-18 stand rejected under 35 U.S.C. §102(b) or alternatively as obvious under 35 U.S.C. §103(a) over Nappholz.

Claim 13 was rejected under 35 U.S.C. §112, first paragraph. Claim 13 has been cancelled.

A. Claim Rejections Based on Thompson and Nappholz

The rejection of claims 1 and 14 on either Thompson or Nappholz is premised on an inherent disclosure that physiological data is analyzed according to a physiological model. In the alternative, Scarantino is relied upon. The limitation at issue is being construed to mean that a comparison of the acquired data to a model. No indication is given as to a specific disclosure in any of the references as to how persons of ordinary skill in the art would recognize that the analysis in Thompson or Nappholz is a comparison of data to a model.

In Thompson, at the remote medical support center, a medical support staff reads telemetry from the implantable medical device and reprograms its operation. See col. 6, lines 2-5. There clearly is no indication of a comparison of acquired data to a physiological model. Instead, the indication is that a medical staff member reviews the data and provides the instructions transmitted to the implantable medical device for reprogramming its operation.

In Nappholz, the repeater programmer provides communication to a remote center where a physician reviews the device data and enters instructions for changing the device functional parameters. See col. 7, lines 59-60. Again, there clearly is no indication of a comparison of acquired data to a physiological model.

Finally, in Scarantino, the status of a tumor undergoing treatment is monitored by tracking of parameters relating to the tumor in evaluation of a treatment strategy. Data transmission from a non-clinical site to a physician interface is provided. Scarantino describes that the evaluation includes determining whether treatment is progressing according to a "predictive model" (col. 13, lines 20-22). The evaluation in Scarantino is described as being based on the deviation of the tumor's response to the delivered therapy at a particular point in time as measured against a population norm.

Claims 1 and 14, as amended, define the physiological model to be a model for long-term disease progression. Support in the specification for this limitation is found at page 8, line 21. As pointed out above, neither Thompson nor Nappholz involves a physiological model at all. The characterization of Thompson and Nappholz as inherently including a model is speculative and unsupported. That comparison to a model may result or could result is insufficient as inherency cannot be established by possibilities or even probabilities. See, *In re Robertson*, 169 f.3d 743, 745 (Fed. Cir. 1999). Moreover, if the sole basis for an obviousness determination rests on a defective finding of anticipation, then the obviousness determination will fall as well. *Id.*

As for a rejection of obviousness based on a combination of either Thompson or Nappholz and Scarantino, there is no indication of the required

showing of a suggestion to combine the references. *In re Dembiczak*, 175 F. 3d 994 (Fed. Cir. 1999). Where there is a failure, as here, to cite specific information in the prior art that would suggest the combination of the prior art references, the rejection is improper as a matter of law. *Id.*

Furthermore, there would be no basis to include a predictive model in either Thompson or Nappholz. Each of Thompson and Nappholz are clear that a medical support staff reviews the acquired implanted medical device data and provides instructions for reprogramming the device.

Yet further, Scarantino cannot be regarded as being within the scope and content of the prior art relevant to the claimed subject matter. To be properly within the scope and content of the relevant prior art, a reference must be reasonably pertinent to the particular problem involved. That is, the prior art must be within the inventor's particular field of endeavor and any analogous art. *Markman v. Lehman*, 987 Fed. Supp. 25, 29 (D.D.C. 1997), *aff'd,* 178 F.3d 1306 (Fed. Cir. 1998). The present invention concerns control of an implantable medical device that delivers therapy to a patient. In Scarantino, a sensor unit is implanted in a patient to monitor a parameter concerning the condition of a tumor. The sensor unit in Scarantino does not concern an implantable medical device delivering therapy to a patient.

B. Conclusion

For the foregoing reasons, claims 1 and 14 and the claims dependent from them should be allowed.

Respectfully submitted,

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MARKED-UP VERSION OF CLAIMS

1. (Twice Amended)A computerized method of controlling one or more implantable medical devices deployed in one or more patients, said implantable medical devices having firmware or software, comprising the steps of:

transmitting via a network communication link a set of historical physiologic data previously gathered from at least [two] one of the implantable medical devices to a centralized computing resource external to a patient;

analyzing the set of historical physiologic data so transmitted according to a suitable physiologic model of long-term disease progression and generating a set of results [of] from the analysis of the set of historical physiological data;

determining a set of instructions comprising an implantable medical device therapy regimen based at least in part on the set of results [of] from the analysis of the set of historical physiologic data; and

transmitting via the network communication link or a separate network communication link the set of instructions to [at least one of] the at least [two] one of the implantable medical devices for execution by the at least one or more implantable medical devices in accordance with a firmware- or a software- implemented executable routine.

4. (Twice Amended) A method according to claim 3 wherein the hybrid link comprises a radio frequency link from said [at least two] implantable medical [devices] device to a routing instrument, and a secondary network link from the routing device to the central computing resource.

14. (Twice Amended) A computerized information network system linking [at least two] an implantable medical [devices] device deployed in [one or

more patients] in a patient to a centralized external computer via a data communication network, said computerized information network comprising:

a central computing resource accessible by the data communication network, said central computing resource capable of applying a physiologic model of long-term disease progression to an aggregate set of patient data recorded by [at least two] the implantable medical [devices] device;

at least one routing instrument capable of wireless communication with [at least one of said at least two] said implantable medical [devices] device deployed in a patient, said at least one routing instrument being capable of performing a data communication sequence with the data communication network.